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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC., Plaintiff, v. UNITED THERAPEUTICS CORPORATION, Defendant.	Civil Action No. 2:19-cv-10170-BRM-JSA

DEFENDANT UNITED THERAPEUTICS CORPORATION'S OFFER OF PROOF

In light of the Court's time and witness limitations at trial, as well as its evidentiary rulings prior to and during trial, Defendant United Therapeutics Corporation ("UTC") submits this Offer of Proof under Federal Rule of Evidence

103. The Offer of Proof outlines certain of the topics to which UTC's witnesses would have testified had they been permitted.

1. **Robert J. Lasek**: Robert J. Lasek is an expert witness retained by UTC with expertise in the pharmaceutical payment process and strategies, specifically with respect to healthcare payers and specialty pharmacies. Mr. Lasek would have testified to relevant topics, including as follows:

    a. The pharmaceutical value chain for a complex specialty drug like treprostinil involves payers, specialty pharmacies, and pharmaceutical manufacturers, all of which have distinct roles. Unlike specialty pharmacies, commercial payers can encourage (*i.e.*, preference)—or even force (*i.e.*, mandate)—use of specific products (*e.g.*, generics). Such preferences and mandates are referred to as "managing the class." Medicare, a government payer, cannot preference or mandate use of a generic drug.

    b. Pharmaceutical manufacturers sometimes can incentivize commercial payers to manage a class of patients. Those incentives typically come in the form of rebates to the payer. However, managing a class is operationally more difficult and resource intensive for therapies that are covered under an insurance plan's medical benefit (which is typically the case for infused treprostinil). As one example, even if a commercial payer updates its medical policy to prefer a generic (a required threshold step), it then needs a way to enforce that preference from an operations perspective. In the case of generic treprostinil, many commercial payers could not enforce a preference or mandate for generic treprostinil because the specialty pharmacy provided them with only the J-code (a billing code), which was shared with Remodulin. This would have been true—the payers could not have enforced a preference or mandate for generic—even if Sandoz launched with both routes of administration, because the shared J-code did not distinguish between brand and generic regardless of the route of administration.

    c. Payers also would be reluctant to manage the class of infused treprostinil patients—even if Sandoz launched with both routes of administration—because of patient fragility, the complexity of the disease, and the small size of the patient population. For example, treprostinil—both brand and generic—are expensive therapies, but the

patient population is small. Thus, the cost to payers is not substantial relative to other costs. As a result, payers could not be expected to preference, let alone mandate, use of generic treprostinil absent sufficient financial incentives in the form of significant rebates. Payers would expect manufacturers to offer a significant (~30%) discount for a generic treprostinil preference, in addition to any discounts that may have been provided to specialty pharmacies.

d. Even if Sandoz launched with both routes of administration and offered rebates to payers, payers would have been highly reluctant to mandate—as opposed to merely preference—use of generic treprostinil because of the particular clinical concerns associated with PAH.

e. Sandoz's payer strategy for the launch of its generic treprostinil was misguided, which impeded its ability to secure market share. Industry standards dictate that a pharmaceutical manufacturer preparing to launch a specialty generic product should demonstrate a clear clinical and economic value proposition for payers—especially if the manufacturer is relying on payers to prefer its product—and engage with payers early to promote awareness and assuage clinical concerns.

f. Sandoz made many mistakes in its payer strategy that impeded its ability to gain preferred status for generic treprostinil, including (1) deciding to partner with specialty pharmacies to the exclusion of payers; (2) choosing not to begin to offer payer rebates until months after launch; and (3) failing to provide key clinical and cost-savings information to payer accounts in advance of launch. For a product like infused treprostinil, payers would not take active steps to encourage generic use absent a more effective strategy than the one Sandoz adopted.

2. **Kevin Gray**: Kevin Gray is formerly UTC's Vice President of Strategic Operations. In addition to the topics Mr. Gray covered at trial, he would have testified to relevant topics, including as follows:

a. UTC's efforts to ensure an adequate supply of delivery devices for Remodulin patients.

b. After Sandoz launched subcutaneous generic treprostinil in May of 2021, UTC experienced only a modest reduction in patients taking

Remodulin. UTC's Remodulin patient base has remained effectively flat since Sandoz launched generic treprostinil, including after it launched a subcutaneous delivery method in May 2021.

c. In response to a looming shortage of CADD-MS 3 cartridges in around 2022-2023, UTC licensed Smiths' cartridge design and other intellectual property, developed an alternative 3mL medication cartridge for use with the CADD-MS 3 pump with a cartridge manufacturer, and with the manufacturer, sought and received FDA clearance of the alternative cartridge. UTC received FDA clearance on that cartridge in approximately three months.

3. **Beth Rhodes**: Beth Rhodes is UTC's Vice President of Global Supply Chain and Alliance Management. Ms. Rhodes would have testified to relevant topics, including as follows:

a. She is responsible for monitoring and managing the usage and supply of CADD-MS 3 pumps and cartridges for Remodulin patients. The average consumption rate of cartridges in 2016 remained roughly consistent across the next few years. The existing inventory of CADD-MS 3 cartridges would have run out before Sandoz's generic launch in 2019. Because of UTC's investment, Smiths Medical reopened CADD-MS 3 production, which created additional supplies that lasted for several additional years.

b. Beginning in 2016, after Smiths Medical had announced the CADD-MS 3 discontinuation and UTC took measures to ensure continued supply of the necessary medical devices for Remodulin patients, UTC began to carefully monitor cartridge quantities. Ms. Rhodes' group was in charge of those monitoring activities. In 2017, as a result of that practice, UTC discovered cartridges were being used up much more quickly than anticipated (in part due to large subsets being used by patients with different disease states). Because of that discovery, UTC paid Smiths Medical to build yet more cartridges (once again, with Smiths Medical's promise that virtually all of those cartridges would be used only by Remodulin patients). Smiths also promised to contract with the specialty pharmacies to ensure cartridges were used only for Remodulin (as was the intent of the contract all along).

c. In her supply chain role, Ms. Rhodes was aware of infusion pumps other than the CADD-MS 3 that were and are used globally to

administer Remodulin subcutaneously. Those pumps included, but are not limited to, the Canè Crono Five, the Medtronic MiniMed Paradigm, the Everaid i-Jet, and the Diamesco Best Life.

4. **Dr. Martine Rothblatt**: Dr. Martine Rothblatt is UTC's CEO, founder, and Board Chair. Dr. Rothblatt would have testified to relevant topics, including as follows:

   a. UTC has long been dedicated to treating and curing PAH. It enjoys a strong reputation in the PAH community, which has promoted significant brand loyalty to UTC's products. Dr. Rothblatt would testify regarding the founding of United Therapeutics with the sole goal of developing therapies to help PAH patients.[1]

   b. Because UTC remains committed to developing new, innovative treatment options for PAH patients, the PAH community remains loyal to UTC and its products. These developments—and others—have led UTC to have a favorable reputation in the PAH community as the leading pharmaceutical company in that space.

   c. Smiths Medical decided to discontinue production of the CADD-MS 3 pump and cartridge. Because UTC's pipeline of next generation delivery devices was not yet ready for patient use, it was concerned that the CADD-MS 3 discontinuation could jeopardize Remodulin patients' ability to receive their medicine. As a result, UTC negotiated with Smiths Medical to reopen manufacturing of the CADD-MS 3 system via the Supply Agreement and its amendments.

   d. UTC entered the Supply Agreement and its amendments with Smiths Medical in order to ensure that Remodulin patients had continued access to their medication. Without the promise of long-term exclusivity of the CADD-MS 3 pumps and cartridges for Remodulin patients, UTC never would have entered that agreement. Smiths Medical was unwilling to reopen production of the CADD-MS 3 pumps or cartridges without a sizeable financial commitment from UTC, which UTC provided.

[1] Dr. Rothblatt's testimony would have been consistent with her account of UTC's history during a public interview at the Boston Children's Hospital. *See* https://www.youtube.com/watch?v=xwBCD222HoA.

5. **Dr. Lisa Shafer**: Dr. Lisa Shafer is an expert witness retained by UTC with expertise in the field of complex pharmaceutical product launches. Dr. Shafer would have testified to relevant topics, including as follows:

   a. Sandoz failed to meet industry standards in its product development work for generic treprostinil, and this failure left Sandoz without an adequate supply of critical delivery devices for its patients at launch. Pharmaceutical devices are often subject to exclusive contracts, and both devices and component parts may become unavailable due to obsolescence. These facts are well known in the industry. As a result, industry standards require that pharmaceutical manufacturers act early in the product development cycle to investigate and, if necessary, to secure an adequate supply of specialized devices needed to administer their products.

   b. Sandoz acted unreasonably in its product development work in a number of ways: First, Sandoz did not begin to investigate an adequate supply of the specialized delivery devices needed until late in the product development cycle. Second, despite knowing that the specialized devices required for subcutaneous administration of its product had been discontinued, Sandoz did not attempt to enter into a contractual agreement to secure an adequate supply of the limited pool of devices or, alternatively, to find another device option. Rather than entering into a written supply agreement to protect against known contingencies, Sandoz relied on vague oral assurances from specialty pharmacies, who had no control of the manufacture of delivery devices or accessories. These actions fell far below industry standards, causing Sandoz costly complications that could have been addressed long before its expected product launch.

6. **Patrick Jones**: Patrick Jones is an expert witness retained by UTC with expertise in the FDA clearance process for medical devices. Mr. Jones would have testified to relevant topics, including as follows:

   a. Sandoz's regulatory response to Smiths Medical's discontinuation of the CADD-MS 3 pump and cartridge fell below industry standards. First, Sandoz unreasonably delayed in responding to news of the CADD-MS 3 discontinuation—something it learned of no later than 2016. Sandoz should have started working on a regulatory response immediately upon learning about the discontinuation. Sandoz should have availed itself of one of the many available options to field an

alternative delivery device, including: (i) importing an international pump used to administer Remodulin and obtaining FDA clearance on it; (ii) modifying an infusion pump and obtaining FDA clearance on it (which is how the CADD-MS 3 originally was developed); (iii) developing a new pump; or (iv) developing an alternative cartridge to be used with the finite, existing supply of CADD-MS 3 pumps (a step Sandoz ultimately took, but not until 2019). Had Sandoz acted promptly, it would have been able to receive FDA clearance for a new delivery device well in advance of its 2019 generic launch.

b. Second, once Sandoz began working in 2019 to receive regulatory clearance on a delivery device, its efforts also fell below industry standards. On average, it takes 129 days for a medical device to receive FDA clearance. Of those 129 days, approximately 72 days are attributed to the FDA's average review time, and approximately 57 are attributed to the time the applicant spends responding to issues and questions raised by the FDA. Sandoz, however, took 283 days to receive clearance on its cartridge—193 of which were attributable to Sandoz's work responding to the many errors the FDA identified in its application. That far exceeded the average time for clearance.

c. Sandoz's 510(k) application and its interactions with the FDA also fell below industry standards. For instance, Sandoz failed to include several basic and rudimentary components in its initial filing, which resulted in the FDA refusing to accept Sandoz's application. Once it corrected those errors, Sandoz then took six months to respond to a set of 21 substantive "major deficiencies" that the FDA identified in the application. Sandoz also ignored the FDA's repeated warnings that it would need to work with Smiths Medical to amend the CADD-MS 3 label such that it would accept Sandoz's new cartridge before the FDA would grant clearance on Sandoz's cartridge. These delays were attributable to Sandoz's failed regulatory efforts and, given the simplicity of the cartridge, it should have been straightforward to obtain clearance within 129 days, or less.

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/s/ Stephen M. Orlofsky

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